

**UNITED STATES DEPARTMENT OF COMMERCE****Patent and Trademark Office**Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/216,641 12/17/98 BURKOTH

T 7010-0001

HM22/0322

EXAMINER

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NIKODEM, D

ART UNIT

PAPER NUMBER

1633

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DATE MAILED:

03/22/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

Commissioner of Patents and Trademarks

**BEST AVAILABLE COPY**

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/216,641	BURKOTH ET AL.
	Examiner David Nikodem	Art Unit 1633

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

30 days

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE \_\_\_\_\_ FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-40 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) \_\_\_\_\_ is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claims 1-40 are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
  - a) All b) Some \* c) None of the CERTIFIED copies of the priority documents have been:
    1. received.
    2. received in Application No. (Series Code / Serial Number) \_\_\_\_\_.
    3. received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

#### Attachment(s)

14) <input type="checkbox"/> Notice of References Cited (PTO-892)	17) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
15) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	18) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
16) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____	19) <input type="checkbox"/> Other: _____

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## DETAILED ACTION

### ***Election/Restrictions***

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Group I, claim(s) 1-14, drawn to methods for delivering particles which comprise a nucleic acid molecule wherein said particles do not include a biolistic core carrier.

Group II, claim(s) 15-40, drawn to methods, pharmaceutical compositions and containers for forming densified particles.

2. In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.
3. The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

- a. The special technical feature of Group 1 is considered to be a method for delivery of nucleic acid molecules, and a composition thereof, to a target tissue or cell using a needleless syringe and wherein the nucleic acid particles do not include a biolistic core carrier.

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- b. The special technical feature of Group II is considered to be a method for forming densified particles.
4. Accordingly, Groups I and II are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept. Furthermore, the groups relate to wholly different methods, with different end results and goals and which utilize wholly different protocols, materials and reagents to practice the invention(s) claimed in each group.
5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).
6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Nikodem whose telephone number is (703) 308-8361. The examiner can normally be reached on M-F, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on (703) 308-0447. The fax phone

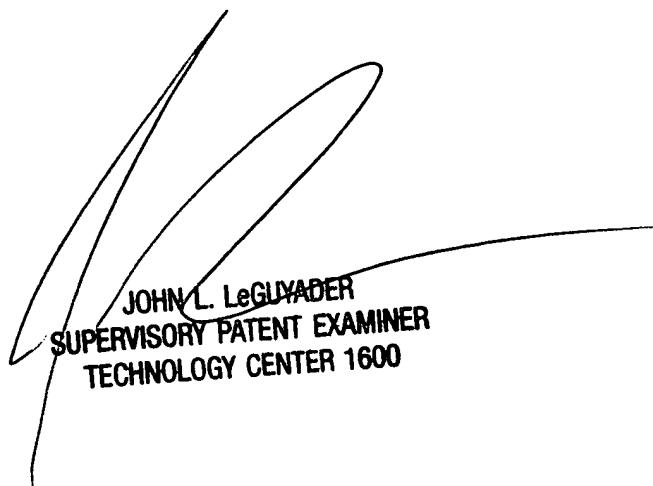
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numbers for the organization where this application or proceeding is assigned are (703) 305-3230 for regular communications and (703) 305-3230 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1123.

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March 21, 2000



JOHN L. LeGLYADER  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600